

BEFORE THE BOARD OF PHARMACY  
DEPARTMENT OF LABOR AND INDUSTRY  
STATE OF MONTANA

In the matter of the amendment of ARM	)	NOTICE OF AMENDMENT,
24.174.301 definitions, 24.174.303	)	ADOPTION, AND REPEAL
internship, 24.174.401 and 24.174.402 fee	)	
schedules, 24.174.501 examination,	)	
24.174.502 transfer, 24.174.503 vaccines,	)	
24.174.524 collaborative practice,	)	
24.174.602 internship, 24.174.604	)	
preceptor requirements, 24.174.801	)	
general licensure, 24.174.804 ownership,	)	
24.174.1122 ambulatory facilities,	)	
24.174.1201 and 24.174.1202 wholesale	)	
licensing, and the adoption of NEW RULE	)	
I pharmacy closure, NEW RULE II change	)	
in location, NEW RULE III change in	)	
ownership, NEW RULE IV, NEW RULE V,	)	
and NEW RULE VI medical gas, NEW	)	
RULE VII change in location, NEW RULE	)	
VIII ownership, NEW RULE IX foreign	)	
interns, NEW RULE X technicians, and	)	
NEW RULE XI centralized prescription	)	
and drug orders, and repeal of 24.174.822	)	
central filling by hub pharmacies	)	

TO: All Concerned Persons

1. On May 24, 2007, the Board of Pharmacy (board) published MAR Notice No. 24-174-56 regarding the proposed amendment, adoption, and repeal of the above-stated rules, at page 636 of the 2007 Montana Administrative Register, issue no. 10.

2. On June 14, 2007, a public hearing was held on the proposed amendment, adoption, and repeal of the above-stated rules in Helena. Several comments were received by the June 22, 2007, deadline.

3. The board has thoroughly considered the comments and testimony received. A summary of the comments and the board's responses are as follows:

ARM 24.174.501 examination for licensure as a registered pharmacist

COMMENT 1: One commenter suggested adding the language from ARM 24.174.502 for foreign candidates to require these students or candidates to take the multistate pharmacy jurisprudence examination (MPJE) and obtain a passing score of not less than 75.

RESPONSE 1: The board notes that foreign candidates are required to take the MPJE and obtain a passing score of not less than 75. ARM 24.174.501(1) and (2) apply to all individuals seeking licensure as a registered pharmacist, whether foreign candidates or not. In order to make this clearer, the board is amending the rule accordingly.

COMMENT 2: One commenter could not locate a minimum level of competency on the Foreign Pharmacy Graduate Equivalency Exam (FPGEE) on the National Association of Boards of Pharmacy (NABP) web site and suggested the board set the passing score rather than leaving it up to NABP.

RESPONSE 2: The board decided not to set forth passing scores in rule because NABP establishes the scores and the board would have to amend the rule following every score change. The board has no control or authority over the content of the NABP web site.

COMMENT 3: A commenter stated that the requirement at (3)(c) for 1500 hours of United States internship may become an issue since all interns must have a social security number and cautioned that some foreign graduates may not be able to obtain a social security number.

RESPONSE 3: The board notes that license applicants are statutorily mandated by 37-1-307(5), MCA, to provide the applicant's social security number as part of the application. The board is amending the rule exactly as proposed.

COMMENT 4: One commenter suggested that the foreign pharmacy graduate requirement be combined with New Rule IX.

RESPONSE 4: In maintaining organizational consistency among the rules, the board decided to keep the internship rules separate from the general licensure rules.

ARM 24.174.502 transfer of license from another state

COMMENT 5: A commenter suggested changing "75" to "75 percent" in (3).

RESPONSE 5: The board proposed no change to the score in the original rule notice, thus the board cannot make any changes to the score in this final notice.

COMMENT 6: One commenter asserted that every U.S. state currently uses the North American Pharmacist Licensure Examination (NAPLEX) and suggested modifying (2) to specifically address the period of time that California did not use the NAPLEX.

RESPONSE 6: The board concluded that there may actually be Montana applicants licensed prior to the inception of NAPLEX who did not take the exam, but who are not from California. The board is amending the rule exactly as proposed.

ARM 24.174.503 administration of vaccines by pharmacists

COMMENT 7: One commenter opposed the amendment to (2)(d) allowing pharmacists to have either a current copy or on-site access to the CDC reference.

RESPONSE 7: In an effort to keep up with current technology, the board decided that it was not necessary to require each pharmacist to purchase a hard copy of the reference every year when the current material is accessible via the computer.

COMMENT 8: Comments were received to relocate the requirements of (9)(b) to ARM 24.174.524 and apply these requirements to all areas covered by collaborative practice agreements.

RESPONSE 8: The board notes that licensed pharmacists must complete the requirements of this rule to qualify to administer vaccines. Qualification to administer vaccines results in an endorsement on the pharmacist's license while being in a collaborative practice does not result in any endorsement. The board did not propose to require training or certification to continue collaborative practice in the original notice and doing so in this final notice would exceed the scope of the original rulemaking. Any additional requirements for collaborative practice participants must be properly noticed and open to public comment in a future rulemaking action. The board will consider the comments for possible future rule changes.

COMMENT 9: Two commenters suggested that the board be more general in the requirements of (9)(b) and not specify the exact hours or types of required continuing education.

RESPONSE 9: The board decided to require a minimum of two hours, but is broadening the acceptable types of education to that approved by the American Council on Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or Continuing Education Advisory Council (CEAC).

COMMENT 10: One commenter suggested modifying (9)(c)(ii) because it is poorly worded.

RESPONSE 10: The board agrees and is amending the rule accordingly.

COMMENT 11: A commenter opposed the requirement that pharmacists certified in vaccine administration obtain two hours of continuing education annually and suggested two hours every two years instead.

RESPONSE 11: The board notes that the CDC offers a brand new two-hour course on immunizations or vaccine-preventable diseases every year and the board lacks a mechanism to conduct audits every two years since renewals are done annually. The board is amending the rule exactly as proposed.

ARM 24.174.524 collaborative practice agreement requirements

COMMENT 12: Several commenters opposed the amendment to (2)(a)(ii) stating that the requirement is contrary to the goal of improving patient access to care. The commenters asserted that the provision would increase barriers for pharmacists to enter into collaborative practice agreements and impair or limit access to care.

RESPONSE 12: The board proposed this amendment in the interest of public safety to require the practitioner and the pharmacist to build and maintain a relationship in which the two collaborate and are in regular contact and communication with one another. The board recognizes that there may be instances where the pharmacist and the practitioner do not practice within the same community but have a relationship consistent with the rule's intent. The board is amending the rule accordingly to allow board consideration of requests for exception to this requirement.

COMMENT 13: One commenter noted that the term "practitioner" is used throughout this rule but is not defined.

RESPONSE 13: The board is amending the rule accordingly to clarify that the term is defined at 37-2-101, MCA.

ARM 24.174.604 preceptor requirements

COMMENT 14: A commenter suggested the board strike "preceptor" from this rule so the ratio change would apply to all pharmacists supervising in a pharmacy whether or not they are preceptors. The commenter wants the board to state how many people a pharmacist in practice can supervise.

RESPONSE 14: As this is a rule specifically delineating preceptor requirements, and the board proposed the amendments to specify that the preceptor requirements apply only to pharmacist preceptors, the board is unable to make the suggested changes at this time. The board did not propose any supervision ratio requirements on nonpreceptor pharmacists in the original notice and doing so in this final notice would exceed the scope of the original rulemaking. Any supervision requirements on nonpreceptor pharmacists must be properly noticed and open to public comment in a future rulemaking action. The board is amending the rule exactly as proposed.

ARM 24.174.804 change in ownership

COMMENT 15: One commenter stated that it appears the board will no longer require the board to approve licenses with an ownership change, and further asserted that the board should review all changes in ownership to ensure compliance with laws mandating who can legally own a pharmacy.

RESPONSE 15: Board staff reviews every application, including every change of ownership, and the full board reviews all nonroutine applications. Following

consideration of the comments, the board is amending the rule to require written notification to the board of all ownership changes between five and 50 percent. A new license will be required when an ownership change exceeds 50 percent.

COMMENT 16: One commenter asserted this rule directly conflicts with 37-2-103, MCA, providing that it is unlawful for a medical practitioner to directly or indirectly own a community pharmacy.

RESPONSE 16: The board disagrees that this rule is in conflict with 37-2-103, MCA, which is unaffected by this rule change and remains in full force and effect.

COMMENT 17: One individual made no comment, but asked how the amendment would affect a pharmacy in the process of negotiating a buy-sell agreement with another individual.

RESPONSE 17: The board is required to be notified in writing of ownership changes from five to 50 percent and a new license is required when ownership changes exceed 50 percent.

#### ARM 24.174.1122 ambulatory surgical facilities

COMMENT 18: One commenter requested further articulation in rule if ambulatory surgical facilities are to be a new license type.

RESPONSE 18: The board concluded that the rule clearly states that these facilities must be registered with the board and is amending the rule exactly as proposed.

#### ARM 24.174.1202 minimum information required for licensure

COMMENT 19: One commenter asserted that (2) is in direct conflict with proposed amendments to ARM 24.174.804 and with 37-2-103, MCA.

RESPONSE 19: The board notes that any change in wholesale drug distributor location must be consistent with New Rule VII and any change in the ownership must be consistent with New Rule VIII and is amending this rule accordingly. The board finds no conflict between this rule and 37-2-103, MCA, as the statute applies to community pharmacies, not wholesale drug distributors.

#### NEW RULE I closure of a pharmacy

COMMENT 20: A commenter stated it is burdensome and unnecessary to require that pharmacies submit to the board a list of controlled substances and the amount transferred upon closure. The commenter stated that pharmacies are accountable to the Drug Enforcement Administration (DEA) for this information and certification that all controlled substances have been disposed of properly is sufficient.

RESPONSE 20: The board proposed this requirement to advance public health and safety and concluded that it is not overly burdensome since the process must be completed for the DEA. The board is amending the rule exactly as proposed.

COMMENT 21: One commenter suggested increasing the time frame for closure notice from 15 to 30 days as a more reasonable requirement as pharmacy closures are very involved processes.

RESPONSE 21: The board concluded that 15 days is more than adequate time to notify the board and is amending the rule exactly as proposed.

#### NEW RULE II change in location

COMMENT 22: One comment was received in support of New Rule II.

RESPONSE 22: The board acknowledges the comment.

#### NEW RULE III change in ownership

COMMENT 23: Two commenters stated that it appears with this new rule the board will no longer approve licenses when there is a change in ownership. The commenters emphasized that the board should review all changes in ownership to ensure compliance with statutes that control who can legally own a pharmacy.

RESPONSE 23: Board staff reviews every application, including every change of ownership, and the full board reviews all nonroutine applications. Following consideration of the comments, the board is amending the rule to require written notice to the board of changes in ownership exceeding five percent. A new license will be required when a change in ownership exceeds 50 percent for all facilities.

COMMENT 24: Two commenters asserted this new rule conflicts with 37-2-103, MCA, and that the board must look at all license applications to determine compliance with the statute.

RESPONSE 24: The board notes that 37-2-103, MCA, prohibiting community pharmacy ownership by medical practitioners, remains unaffected by this new rule that regulates ownership change of mail service pharmacies.

#### NEW RULE VIII change in ownership

COMMENT 25: One commenter stated that it appears with this new rule the board will no longer approve licenses when there is a change in ownership. The commenter asserted that the board should review all ownership changes.

RESPONSE 25: Board staff reviews every application, including every change of ownership, and the full board reviews all nonroutine applications. Following consideration of the comment, the board is amending the rule to require written

notification to the board of all ownership changes between five and 50 percent. A new license will be required when a change in ownership exceeds 50 percent. The board notes that 37-2-103, MCA, prohibiting community pharmacy ownership by medical practitioners, remains unaffected by this new rule that regulates ownership change of wholesale drug distributors.

#### NEW RULE IX foreign intern requirements

COMMENT 26: One commenter asked if this new rule could be combined with the foreign intern requirement of ARM 24.174.501.

RESPONSE 26: The board acknowledges that the foreign pharmacy graduate requirement in ARM 24.174.501(3) could be combined with this new rule. However, the rules regarding internships are separate from the general licensure rules and the board desires to maintain this consistency within the rules.

COMMENT 27: Two commenters stated that the MPJE is missing and needs to be added to this new rule, along with a logical passing score.

RESPONSE 27: The board disagrees as foreign interns are not required to take and pass the MPJE in order to obtain a pharmacy intern license.

COMMENT 28: One commenter questioned the use of the term "student," in (2) because at that time, the person may no longer be a student.

RESPONSE 28: The board determined that the term "intern" is more accurate and is amending the rule accordingly.

COMMENT 29: A commenter stated the rule should explain why there must be an appearance before the board.

RESPONSE 29: The board respectfully disagrees and is not amending the rule to include this explanation.

COMMENT 30: A commenter questioned whether this rule should cover both graduates and undergraduates.

RESPONSE 30: The rule applies to graduates of a foreign school of pharmacy. The board declines to amend the rule to include undergraduates as one must be a graduate to take the MPJE and FPGEE.

#### NEW RULE X technician check technician program

COMMENT 31: Two commenters questioned use of the term "institutional" and asked to which facilities this rule will apply. One commenter suggested requiring that the pharmacy be either licensed as an institutional pharmacy or contract for

services with an institutional pharmacy since not all institutional pharmacies have their own actual internal pharmacy.

RESPONSE 31: The board agrees and is amending the rule to specify the requirements for technician check technician (TCT) programs apply to institutional pharmacies within a hospital and that any facility not within an institutional pharmacy within a hospital must seek board approval.

COMMENT 32: One commenter suggested deleting (1)(b) through (6) stating that the requirements would be considered within the utilization plan for technicians where a TCT program is a component.

RESPONSE 32: The board respectfully disagrees and notes that a TCT program and a utilization plan are two separate and distinct things. The board is retaining the guidelines for the TCT program in (1)(b) through (6) exactly as proposed.

COMMENT 33: One commenter opposed the requirement that TCT training programs perform quality assurance audits quarterly for the first year and then every six months thereafter as totally insufficient.

RESPONSE 33: The board notes that the TCT pilot projects last six months and have been shown to be successful and have adequate supervision within that reasonable time frame. Further, the board only meets four times per year.

COMMENT 34: A commenter asserted that the board cannot govern the redirecting of pharmacists from distributive tasks to cognitive tasks as they lack jurisdiction over the FTE distribution in any facility or institution.

RESPONSE 34: The board respectfully disagrees and reiterates that the primary intent behind TCT programs is to allow pharmacists to have more time to counsel than dispense.

NEW RULE XI centralized prescription filling and processing of drug orders  
and repeal of ARM 24.174.822 central filling by hub pharmacies

COMMENT 35: One commenter suggested striking (5) and instead require that the contract between the two pharmacies clearly designate the duty to counsel the patient either to the central filling or to the delivering pharmacy.

RESPONSE 35: The board concluded that it is in the interest of patient safety for the delivering pharmacy to provide patient counseling and is amending the rule exactly as proposed.

COMMENT 36: One commenter opined that (5) contradicts (9)(a)(v) through (vii) that requires all of these functions be delegated in policy and procedure and does not state the responsibilities of each pharmacy.

RESPONSE 36: The board determined that all pharmacy duties are critical and necessarily outlined in a policy and procedure manual. The board found no contradiction in that (5) mandates that the delivering pharmacy provide counseling while (9) simply lists all the responsibilities that must be outlined in the manual.

COMMENT 37: One commenter suggested the board delete (2)(a), (2)(b), and (3), removing the notice to the patient of possible outsourcing and the patient's choice not to outsource. The commenter stated this would prevent the unnecessary confusion of patients when trying to explain outsourcing. The commenter also requested that the board clarify that (9)(c)(iv) concerns central filling and processing.

RESPONSE 37: The board respectfully disagrees and stresses the importance of retaining these provisions to strengthen and support the patient's choice in outsourcing. Subsection (9)(c)(iv) is found within the central filling rule and the board concluded that further clarification is not necessary. The board is amending the rule exactly as proposed.

COMMENT 38: One commenter suggested adding a requirement that whenever pharmacists from two different pharmacies electronically share prescription processing, each pharmacist will be electronically notified.

RESPONSE 38: The board notes that when verifying the prescription at the end of the process, the pharmacist will know where it was last filled and can track where it went. The board is amending the rule exactly as proposed.

4. The board has amended ARM 24.174.301, 24.174.303, 24.174.401, 24.174.402, 24.174.502, 24.174.602, 24.174.604, 24.174.801, 24.174.1122, and 24.174.1201 exactly as proposed.

5. The board has adopted NEW RULE I (24.174.807), NEW RULE II (24.174.1004), NEW RULE IV (24.174.1204), NEW RULE V (24.174.1205), NEW RULE VI (24.174.1206), NEW RULE VII (24.174.1207), and NEW RULE XI (24.174.823) exactly as proposed.

6. The board has repealed ARM 24.174.822 exactly as proposed.

7. The board has amended ARM 24.174.501, 24.174.503, 24.174.524, 24.174.804, and 24.174.1202 with the following changes, stricken matter interlined, new matter underlined:

24.174.501 EXAMINATION FOR LICENSURE AS A REGISTERED PHARMACIST (1) and (2) remain as proposed.

(3) Pharmacy graduates from outside the 50 states, the District of Columbia, or Puerto Rico, who seek certification of educational equivalency in order to sit for the North American pharmacist licensure examination must also complete the following:

(a) through (4) remain as proposed.

AUTH: 37-1-131, 37-7-201, MCA

IMP: 37-1-131, 37-7-201, 37-7-302, MCA

24.174.503 ADMINISTRATION OF VACCINES BY PHARMACISTS

(1) through (9)(a) remain as proposed.

(b) participate in a minimum of two hours of ACPE or CME accredited continuing education on immunizations or vaccine-preventable diseases every year. The continuing education must be American Council on Pharmaceutical Education (ACPE), Continuing Medical Education (CME), or Continuing Education Advisory Council (CEAC) approved; and

(c) and (c)(i) remain as proposed.

(ii) ~~have~~ having a Montana licensed health care provider authorized to prescribe or administer vaccines or ~~have~~ an immunization-certified pharmacist witness and validate the pharmacist's vaccine administration technique every year.

(10) remains as proposed.

AUTH: 37-7-101, 37-7-201, MCA

IMP: 37-7-101, 37-7-201, MCA

24.174.524 COLLABORATIVE PRACTICE AGREEMENT REQUIREMENTS

(1) through (2)(a) remain as proposed.

(i) the practitioner as defined in 37-2-101, MCA, must be licensed in good standing in Montana; and

(ii) the practitioner must be in active practice in the community in which the collaborating pharmacist practices. A request for an exception to this provision must be in writing and will be decided by the board.

(b) through (4) remain as proposed.

AUTH: 37-7-201, MCA

IMP: 37-7-101, 37-7-201, MCA

24.174.804 CHANGE IN OWNERSHIP (1) and (2) remain as proposed.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

AUTH: 37-7-201, MCA

IMP: 37-7-201, 37-7-321, MCA

24.174.1202 MINIMUM INFORMATION REQUIRED FOR LICENSURE

(1) remains as proposed.

(2) Any changes in information contained in (1) ~~(a) through (f)~~ shall be submitted to the board within 30 days of the change. Any changes in location or ownership require that a new license application be filed with the board at least 30 days prior to the change.

AUTH: 37-7-201, 37-7-610, MCA  
IMP: 37-7-604, 37-7-605, MCA

8. The board has adopted NEW RULE III (24.174.1005), NEW RULE VIII (24.174.1208), NEW RULE IX (24.174.605), NEW RULE X (24.174.715), with the following changes, stricken matter interlined, new matter underlined:

NEW RULE III (24.174.1005) CHANGE IN OWNERSHIP (1) and (2) remain as proposed.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

AUTH: 37-7-201, 37-7-712, MCA  
IMP: 37-7-701, 37-7-702, 37-7-703, 37-7-704, 37-7-706, MCA

NEW RULE VIII (24.174.1208) CHANGE IN OWNERSHIP (1) and (2) remain as proposed.

(3) The board must be notified in writing when five to 50 percent of the equitable ownership of a business is transferred in a single transaction or in a related series of transactions to one or more persons or any other legal entity.

AUTH: 37-7-201, 37-7-610, MCA  
IMP: 37-7-604, 37-7-605, MCA

NEW RULE IX (24.174.605) FOREIGN INTERN REQUIREMENTS

(1) remains as proposed.

(2) The ~~student~~ intern and their preceptor must appear before the board.

(3) and (4) remain as proposed.

AUTH: 37-1-131, 37-7-201, MCA  
IMP: 37-7-201, MCA

NEW RULE X (24.174.715) TECHNICIAN CHECK TECHNICIAN

PROGRAM (1) To participate in a technician check technician (TCT) program an institutional pharmacy within a hospital must meet the following requirements:

(a) through (6) remain as proposed.

(7) Any facility that is not within an institutional pharmacy within a hospital must come before the board.

AUTH: 37-7-201, MCA  
IMP: 37-7-101, 37-7-201, 37-7-301, 37-7-307, MCA

BOARD OF PHARMACY  
MARK MEREDITH, Pharm. D.

/s/ DARCEE L. MOE  
Darcee L. Moe  
Alternate Rule Reviewer

/s/ KEITH KELLY  
Keith Kelly, Commissioner  
DEPARTMENT OF LABOR AND INDUSTRY

Certified to the Secretary of State November 13, 2007